

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

IN RE ST. JUDE MEDICAL, INC., :
SILZONE HEART VALVES PRODUCTS :
LIABILITY LITIGATION :

MDL DOCKET NO. 1396

JOINT STATUS CONFERENCE REPORT

The parties have met and conferred and submit the following status report to the Court.

1. STATUS OF PLEADINGS

The parties have agreed to amend the caption of the Consolidated Amended Class Action Complaint to correct the name of class representative Joe W. Sanchez. An executed stipulation was recently forwarded to the court for signature.

2. STATUS OF CLASS DISCOVERY

A. Class Representative Depositions

St. Jude Medical has completed the depositions of class representatives Beatrice Bailey, Lester Grovatt and Joe W. Sanchez. The deposition of Levy Redden is

scheduled for March 26, 2002. The deposition of Bonnie Sliger is scheduled for March 29, 2002.

B. St. Jude Medical Employee Depositions

At the last Status Conference, this Court authorized plaintiffs to depose certain of St. Jude Medical's employees with regard to class issues. In this regard, plaintiffs have completed the depositions of Laxmi Peri and Juan Cristiani. The depositions of St. Jude Medical's employees currently scheduled for purposes of class certification are as follows:

DATE	DEPONENT
March 19, 2002 (1:00 p.m.)	William Holmberg
March 19, 2002 (3:00 p.m.)	Karen McKelvey
March 20, 2002 (9:00 a.m.)	Alan Flory
March 20, 2002 (1:30 p.m.)	Steven Healy
March 21, 2002 (9:00 a.m.)	Denise Johnson
March 21, 2002 (1:30 p.m.)	Louann Carpenter
March 22, 2002 (9:00 a.m.)	Don Guzik
March 22, 2002 (1:30 p.m.)	Matthew Ogle

C. Other Depositions

Two depositions have been noticed by state court attorneys for plaintiffs' in the matter of *Bridges v. St Jude Medical, Inc.*. Dr. Gary Grunkemeier, a biostatistician, has been noticed for Friday, April 12, in Portland, Oregon and Dr. Jagdish Butany, a Canadian pathologist is scheduled for Friday, April 26th. These are merits depositions. St Jude Medical, Inc. has issued notices indicating it intends to cross-notice these depositions in the MDL.

D. Status of Written Discovery

By the time of the Status Conference, St. Jude Medical contends it will have substantially completed its production of documents in response to plaintiffs' First Request for Production of Documents Regarding Class Issues.

On March 8, 2002, St. Jude Medical provided supplemental responses to plaintiffs' First Set of Interrogatories Regarding Class Issues. In those responses, St. Jude Medical contends it specifically identified the documents which contain the factual support for the legal arguments St. Jude Medical will make in opposition to class certification. St. Jude Medical also identified 2 lay and 2 expert witnesses which may testify by affidavit at the class certification hearing. St. Jude Medical has represented that it will supplement these responses on an ongoing basis as additional documents and witnesses are identified.

Pretrial Order No. 10 also required plaintiffs to designate by March 8, 2002 lay

witnesses but will provide the names to St. Jude Medical as soon as they are known to them.

E. Status of FDA Subpoena

St. Jude Medical has advised Class counsel that, on March 12, 2002 the FDA delivered a CD Rom containing documents responsive to Class counsel's subpoena, that St. Jude Medical was going to review the documents in accordance with PTO 9 and that thereafter St. Jude Medical will provide the CD Rom to class counsel. Further, additional documents are being sent by the FDA, the exact date of delivery is unknown.

3. STATUS OF PRETRIAL ORDERS

A. Preservation Orders

The parties have reached agreements on Pretrial Order Nos. 6 and 7 governing the preservation of explanted heart valves and electronic data, respectively. Those orders were entered by the Court on March 1, 2002.

B. Order Authorizing Sharing of Documents Between U.S. and Canadian Plaintiffs Counsel

The parties have reached an agreement on Pretrial Order No. 11 authorizing MDL plaintiffs' counsel in the United States and Canadian plaintiffs' counsel to share St. Jude Medical's confidential documents. Pretrial Order No. 11 has been submitted to the Court for execution.

**C. Order Requiring St. Jude Medical To Inform Plaintiffs Of
Depositions of St. Jude Medical's Employees In Other Jurisdictions**

The parties have reached an agreement on a pretrial order requiring St. Jude Medical to notify plaintiffs when depositions of St. Jude Medical's employees (past and present), directors and expert witnesses are noticed in other jurisdictions and to produce transcripts of all such depositions. Pretrial Order No. 13 has been submitted to the Court for execution.

**D. Order Prohibiting St. Jude Medical From Communicating With
Putative Class Members**

Plaintiffs have proposed Pretrial Order No. 12 prohibiting St. Jude Medical from initiating any contact whatsoever, whether written, oral or otherwise, with any member of putative Class I or putative Class II, as such terms are defined in the Plaintiffs' Consolidated and Amended Class Action Complaint. The proposed order also seeks to prohibit St. Jude Medical from seeking the return to St. Jude Medical of any explanted Silzone heart valve without first having received the express written authorization and consent of the individual patient from whom such Silzone valve was explanted. A copy of plaintiffs' proposed Pretrial Order 12 is attached.

St. Jude Medical contends that prior to class certification, "[d]efendants ordinarily are not precluded from communications with putative class members." Manual for Complex Litigation, Third, §30.24 at 233; see also Gulf Oil v. Bernard, 452 U.S. 89 (1981).

St. Jude Medical also contends that orders limiting or restricting communications

with putative class members may only be made on "a clear record and specific findings that reflect a weighing of the need for a limitation and the potential interference with the rights of the parties" which results in a "carefully drawn order that limits speech as little as possible, consistent with the rights of the parties under the circumstances." Gulf Oil v. Bernard, 452 U.S. 89 (1981); see also Manual for Complex Litigation, Third, §30.24 at 233.

St. Jude Medical has represented to plaintiffs and this Court that it is not initiating direct contact with putative class members. St. Jude Medical contends that plaintiffs have not demonstrated a need for any further limitations. Notwithstanding, St. Jude Medical states that with respect to initiating direct contact with putative class members, it is willing to be governed by the terms of its proposed Pretrial Order No. 12 which is attached to this report.

St. Jude Medical also contends that to the extent plaintiffs are seeking to prohibit St. Jude Medical from inspecting an explanted Silzone® heart valve without first having received the express written authorization and consent of the individual from whom such Silzone® valve was explanted, such would unduly interfere with St. Jude Medical's duties under federal law to investigate adverse events associated with the Silzone® valve.

Plaintiffs take exception to this position and contend that St. Jude Medical has not indicated how it would interfere with their duties. Plaintiffs contend that the explanted Silzone valves belong to the affected patients and most will undoubtedly be

cooperative with the valve testing if adequate safeguards of their rights are in place.

St. Jude Medical responds that it has advised plaintiffs that St. Jude Medical cannot properly fulfill its obligations under Medical Device Reporting regulatory requirements unless it can inspect explanted valves. St. Jude Medical contends that requiring it to obtain permission from the patient before inspecting the valve would effectively thwart this process. Plaintiffs challenge this assertion and seek an explanation of how the process would be thwarted.

St. Jude Medical has also advised plaintiffs that Paragraph 3 of plaintiffs' proposed order is inconsistent with PTO 6. St. Jude Medical contends that PTO 6, which was stipulated to by the parties, allows SJM to inspect explanted heart valves pursuant to the protocol without having to obtain permission of the patient. Plaintiffs disagree that PTO 6 allows for inspection of explanted valves without permission. St. Jude Medical contends that Paragraph 3 of plaintiffs' proposed order effectively modifies PTO 6 by requiring St. Jude Medical to obtain the permission of the patient before inspecting the valve.

4. CASE STATUS REPORT

A current report on federal and state court filings as prepared by St. Jude Medical was forwarded to the Court by electronic mail on March 13, 2002.

5. APPOINTMENT OF STATE LIAISON COMMITTEE

Plaintiffs contend that due to the significant increase in the number of state court

cases filed, it would be prudent and allow for the effective judicial management of the litigation to establish a committee to coordinate the activities of the federal MDL and the various state court actions. Plaintiffs will submit a proposed order for the court to sign appointing Pat Murphy as the Chair of the State Liaison Committee.

6. AMENDMENT TO PTO 2

At the status conference scheduled for Tuesday March 19, 2002, the parties will provide the Court with a revised Pretrial Order No. 2 setting forth the dates agreed upon for class discovery, submission of briefs and the class certification hearing.

DATED:

LEVY, ANGSTREICH, FINNEY,
BALDANTE, RUBENSTEIN & Coren, P.C.

By

Steven E. Angstreich
Co-Lead Counsel for Plaintiffs

DATED:

CAPRETZ & ASSOCIATES

By

James T. Capretz
Co-Lead Counsel for Plaintiffs

DATED:

ZIMMERMAN REED, P.L.L.P

By _____
J. Gordon Rudd, Jr., No. 222082
Plaintiffs' Liaison Counsel

GREEN SCHAAF & JACOBSON, P.C.

By _____
Joe D. Jacobson
Lead Counsel for Class II Plaintiffs

DATED:

CROSBY, HEAFEY, ROACH & MAY
Professional Corporation

By _____
David E. Stanley
Attorneys for Defendant
St. Jude Medical, Inc.